

Part VI: Summary of the risk management plan

Summary of risk management plan for [Dexamethasone] 1mg/ml eye drops, solution

This is a summary of the risk management plan (RMP) for [Dexamethasone] 1mg/ml eye drops, solution, how these risks can be minimised, and how more information will be obtained about [Dexamethasone] 1mg/ml eye drops, solution risks and uncertainties (missing information).

[Dexamethasone] 1mg/ml eye drops, solution summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Dexamethasone] 1mg/ml eye drops, solution should be used.

Important new concerns or changes to the current ones will be included in updates of [Dexamethasone] 1mg/ml eye drops, solution' RMP.

I. The medicine and what it is used for

[Dexamethasone] 1mg/ml eye drops, solution is a preservative-free eye drops solution authorised for treatment of the inflammation of the eye. The eye should not be infected (red eye, secretions, tearing, etc.), otherwise a specific treatment of patient's infection should be combined.

It contains dexamethasone as the active substance and is given by ophthalmic administration (ocular).

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of [Dexamethasone] 1mg/ml eye drops, solution, together with measures to minimise such risks and the proposed studies for learning more about [Dexamethasone] 1mg/ml eye drops, solution's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

Important risks of [Dexamethasone] 1mg/ml eye drops, solution are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of [Dexamethasone] 1mg/ml eye drops, solution. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

The safety information in the Product Information is aligned to the reference medicinal product Monopex Eye drops, solution 1mg/ml in single-dose container (Laboratoires THEA).

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of [Dexamethasone] 1mg/ml eye drops, solution.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for [Dexamethasone] 1mg/ml eye drops, solution.